LumiQuick Diagnostics, Inc.
2946 Scott Blvd., Santa Clara, CA 95054

510(k) SUMMARY
AS REQUIRED BY SECTION 807.92(C)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92(C)

The Assigned 510(k) number is: k130213

Date of Summary: October 8, 2013

OCT 18 2013

Common Name: Drugs of Abuse Screening Device

Regulatory Information:

1. Regulation section: 21 CFR part 862.3870 (THC), 21 CFR part 862.3250 (COC), 21 CFR part 862.3650 (OPI), 21 CFR part 862.3100 (AMP), 21 CFR part 862.3170 (BZO), 21 CFR part 862.3610 (MAMP), 21 CFR part 862.3620 (MTD), 21 CFR part 862.3150 (BAR), non-applicable for PCP
2. Classification: Class II, Unclassified (PCP)
3. Product Codes: LDJ (THC), DIO (COC), LCM (PCP), DJG (OPI), DKZ (AMP), JXM (BZO), DJC (MAMP), DJR (MTD), DIS (BAR)
4. Panel: Toxicology (91)

Applicant and Initial Importer:

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Contact Persons:

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510(k) SUMMARY (Cont.)
AS REQUIRED BY SECTION 807.92(C)

Identification / Product Name:
QuickProfile™ Single Drug of Abuse Screen Device
Quick Profile™ Multi-Drugs of Abuse Screen Device

Description:
One-step, colloidal gold based chromatographic immunoassay for the rapid, qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Methadone, Methamphetamine, Opiates, Phencyclidine, and Marijuana in human urine.

Intended Use:
The LumiQuick's QuickProfile™ Single Drugs of Abuse and QuickProfile™ Multi-Drugs of Abuse Screen Devices are rapid chromatographic immunoassays for the qualitative and simultaneous detection of one to nine of the following drugs in a variety of combinations in human urine. Both devices are available in test strip, dip panel, cassette panel and cup formats. The designed cutoff concentrations and direct calibrator for these drugs are as follows:

AMP	**Amphetamine**	**1000 ng/ml**
BAR	**Secobarbital**	**300 ng/ml**
BZO	**Oxazepam**	**300 ng/ml**
COC	**Benzoylecgonine**	**300 ng/ml**
MTD	**Methadone**	**300 ng/ml**
MAMP	**Methamphetamine**	**1000 ng/ml**
OPI	**Morphine**	**300 ng/ml**
PCP	**Phencyclidine**	**25 ng/ml**
THC	**THC 11-nor-Δ^9-THC-9-COOH**	**50 ng/ml**

These devices are intended for prescription use only. These assays provide only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory method.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Substantial Equivalence (Predicate Kit):
LumiQuick's QuickProfile™ Single Drugs of Abuse and QuickProfile™ Multi-Drugs of Abuse Screen Devices are substantially equivalent to the predicate device noted below:

Device Name: Innovacon Spectrum II
510(k) numbers for predicate devices are: k061718

510(k) SUMMARY (Cont.)
AS REQUIRED BY SECTION 807.92(C)

Summary of Device Similarities and Differences
The predicate device and the subject device are identical in functionality and performance. A comparison chart outlining the similarities and differences between the predicate and subject device is shown below:

Similarities and Differences		
Item	QuickProfile (Subject Device)	Innovacon (Predicate Device k061718)
Indications for Use	*Professional Use (non-POC)*	*Professional Use (POC)*
Device Format	*Test strip, Dip panel, Cassette panel, and Cup*	*Test Card; Cup*
Device Technology	Immunoassay	
Test Time	5 minutes	
Cutoff Levels	Same	
Storage Conditions	Transportation and Storage Temperature: 2-30 ℃ Transportation Storage Humidity: N/A (sealed in pouch)	
Unit of measure	ng/ml	
Sample type	Urine	
Testing procedure	Same	
Result(s) Interpretation	Visual	
Sample Application	Same	
Control Solution	Non-Applicable	
Calibration	N/A	

Statement of No Differences:
For the reasons mentioned above, it is concluded that the Subject devices are substantially equivalent to the predicate device in commercial distribution, with respect to indications for use and technology.

510(k) SUMMARY (Cont.)
AS REQUIRED BY SECTION 807.92(C)

Technology Characteristics:
The DOA Screen Devices are one-step immunoassays in which chemically labeled drugs (drug-protein conjugates) compete for limited antibody binding sites with drugs that may be present in urine. The single and multi-test devices contain one or more than one test strips (single drug or 2-in-1 drugs per test strip) in the dip panel, cassette panel and cup formats. The drug-protein conjugates are pre-coated on the test band of the membrane and the drug antibody-colloidal gold conjugate pads are placed at one end of the membrane. In the absence of drugs in the urine, the solution of the colored antibody-colloidal gold conjugates move along with the sample solution upward chromatographically by capillary action across the membrane to the immobilized drug-protein conjugate zones on the test band region. The colored antibody-gold conjugates then attach to the drug-protein conjugates to form visible lines as the antibodies complex with the drug conjugates. Therefore, the formation of the visible precipitant in the test band occurs when the test urine is negative for the drug. When drug is present in the urine, the drug/metabolite antigen competes with drug-protein conjugates on the test band region for the limited antibody on the colored drug antibody-colloidal gold conjugate pad. When a sufficient concentration of the drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody (drug-protein conjugate)-colloidal gold conjugate to the drug-protein conjugate zone on the test band region. Therefore, absence of the color band on the test region indicates a positive result.

Discussion of Non-clinical Test Performed:
Non-clinical tests were evaluated to establish the performance, functionality, safety and reliability of the QuickProfile™ devices. The performance evaluations include: Sensitivity, Precision (usability), Stability (Device and Specimen), Reading Time, Specificity and Interference.
These studies evaluations were performed internally by professional personnel in LumiQuick Diagnostics, by qualified lab personnel, with proper calibrated / maintained lab equipments and under properly-controlled environmental conditions according to study requirements. All of the evaluated performances passed and meet the acceptance criteria set in the study protocol.

Discussion of Clinical Tests Performed:
The Accuracy and Comparison Study was performed by comparing the GC/MS confirmed drug concentration on the QuickProfile™ devices and Predicate kit, using unaltered urine specimens, by lab professionals.
Minimum of 87 urine specimens were evaluated per drug, the study results demonstrate 100% accuracy between subject device and GC/MS confirmation level.

510(k) SUMMARY (Cont.)
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Performance:
The product performance characteristics of LumiQuick's QuickProfile™ Single Drugs of Abuse and QuickProfile™ Multi-Drugs of Abuse Screen Devices were evaluated in the blind- labeled clinical specimen correlation study and in the blind-labeled spiked control studies including sensitivity, precision study, etc. Results of these studies demonstrate substantial equivalence between LumiQuick's QuickProfile™ Single Drugs of Abuse and QuickProfile™ Multi-Drugs of Abuse Screen Devices, GC/MS confirmation methodology, as well as Predicate device.

Conclusion:
Results of Accuracy, Sensitivity, Precision, Specificity, Interference studies demonstrate substantial equivalence between LumiQuick's QuickProfile™ Single Drugs of Abuse and QuickProfile™ Multi-Drugs of Abuse Screen Devices and the Predicate device. Results also demonstrate that LumiQuick's QuickProfile™ Single Drugs of Abuse and QuickProfile™ Multi-Drugs of Abuse Screen Devices are safe and effective in detecting Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Methadone, Methamphetamine, Opiates, Phencyclidine, and Marijuana in human urine specimen, for Professional (Non-POC) use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 18, 2013

LumiQuick Diagnostics, Inc.
C/O Feng-Yu Lee
IVDD Regulatory Consultant
27001 La Paz Rd., Suite 266B
MISSION VIEJO CA 92691

Re: K130213
Trade/Device Name: QuickProfile™ Single Drugs of Abuse Screen Device
QuickProfile™ Multi-drugs of Abuse Screen Device
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: II
Product Code: LDJ, DIO, LCM, DKZ, JXM, DJG, DJC, DJR, DIS
Dated: August 29, 2013
Received: September 06, 2013

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k130213

Device Name: QuickProfile Single Drugs of Abuse Screen Device
QuickProfile Multi-Drugs of Abuse Screen Device

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PCP	Phencyclidine	25 ng/ml
THC	THC 11-nor-Δ^9-THC-9-COOH	50 ng/ml

Prescription Use __X____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k130213

Indications for Use

510(k) Number (if known): k130213

Device Name: QuickProfile Single Drugs of Abuse Screen Device
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(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

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Denise Johnson-lyles -S

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